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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,499	06/05/2001	James E. Kipp	1417Y P 478	6158

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EXAMINER

OH, SIMON J

ART UNIT PAPER NUMBER

1615

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/874,499	Applicant(s) KIPP ET AL.	
	Examiner Simon J. Oh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicants' request for continued examination, amendment, response, and petition for extension of time, all received on 29 March 2004.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-17 under 35 U.S.C. 103(a) as being unpatentable over Stainmesse *et al.* is withdrawn.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stainmesse *et al.* in view of Cima *et al.* (U.S. Patent Application Publication No. 2002/0048610 A1)

The Stainmesse *et al.* patent teaches methods of producing nanoparticles comprising first, preparing a liquid phase consisting essentially of a solution of the substance in a solvent or in a mixture of solvents to which may be added one or more surfactants; second, preparing a second liquid phase consisting essentially of a non-solvent or a mixture of non-solvents for the substance and to which may be added one or more surfactants, the non-solvent or the mixture of non-solvents for the substance being miscible in all proportions with the solvent or the mixture of solvents for the substance; third, adding one of the liquid phases prepared in first or second step to the other with moderate stirring so as to produce a colloidal suspension of nanoparticles of the

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substance; and fourth, if desired, the removal of all or part of the solvent or the mixture of solvents for the substance and of the non-solvent or the mixture of non-solvents for the substance so as to produce a colloidal suspension of nanoparticles of the desired concentration or to produce a powder of nanoparticles (See Abstract; Column 2, Lines 32-52; and Claim 1). Various organic compounds may serve as the substance in the disclosed process, including polymers, waxes, biologically active substances, or pigments (See Column 2, Line 60 to Column 3, Line 38).

The Stainmesse *et al.* patent does not teach more specific methods of controlling crystal properties in the production of nanoparticles.

The Cima *et al.* publication discloses various method steps used to produce crystals of a particular substance possessing certain desired characteristics (See Abstract). Various components that assist in the disclosed methods are disclosed. The addition of non-solvents to influence the growth of crystals is disclosed (See Sections [0114] and [0115]). The use of various additives, such as surfactants, solvents, seed crystals, impurities, and other excipients is disclosed for the purpose of promoting or controlling nucleation and for influencing various crystal properties, such as crystal habit, polymorphic form (including amorphous particles), and particle size (See Sections [0014] to [0028], and [0119] to [0132]). The role of adjusting processing parameters for the purpose of influencing the product created by the disclosed methods is also disclosed. Such parameters include temperature, and its influence in altering the state of saturation; time, particularly its role in “ageing”; pH, and its role in determining the physical state and properties of the solid phase; and concentration, particularly the role of supersaturation in influencing the nucleation and growth rate of crystals. Various processing

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steps are also disclosed, including stirring, filtering, centrifuging, and the input of various types of energy, such as mechanical stimulation, ultrasound, and laser energy (See Sections [0182] to [0185] and [0188] to [0194]). The induction of nucleation by various process steps is disclosed, such as the input of energy, the addition of surfactants, and the alteration of the state of saturation. The induction of precipitation by various process steps is disclosed as well, including the addition of a non-solvent (See Sections [0201] to [0207]). Various analytical methods are also disclosed, including differential scanning calorimetry, or DSC (See Section [0266]), as well as X-ray diffraction (See Section [0221]). Various pharmaceuticals, suitable for the disclosed methods are also listed, itraconazole among them (See Section [0088], particularly Page 7, 1st Column, 4th Line).

It would be obvious to one of ordinary skill in the art to combine the teachings of Stainmesse *et al.* and Cima *et al.* into the objects of the instantly claimed invention. One of ordinary skill would be motivated to modify the disclosure of Stainmesse *et al.* in view of Cima *et al.* in order to gain greater control of product characteristics, including size and morphology. It is the position of the examiner that one of ordinary skill would be able to use the disclosure of the prior art to create suspensions and particles in accordance with the instantly claimed invention through routine experimentation, with a reasonable expectation of success. Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 29 March 2004 have been fully considered but they are not persuasive.

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The disclosure of the Cima *et al.* reference shows how one of ordinary skill in the art can influence the polymorphic form of the crystals produced by the methods described therein. It is the position of the examiner that with the combined disclosure of the prior art, one of ordinary skill can produce non-spherical sub-micron-sized particles.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1615

sj0

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